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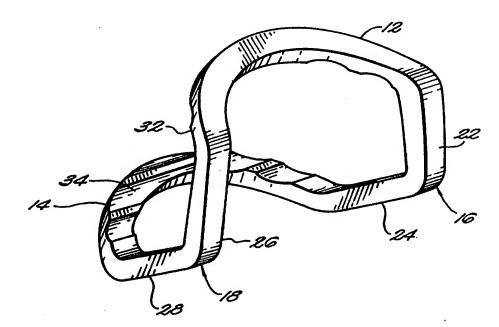
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(54) Title: SURGICAL VESSEL CLIPS AND METHODS FOR CLOSING VESSELS

(57) Abstract

The application addresses the need for novel hemostatic clips that are used advantageously when control of a vessel has not been obtained or when a vessel is lacerated or divided inadvertently. These clips urge closure of a perforation in the wall of a vessel, and reduce the necessity for suturing the vessel. In addition, the disclosure addresses the need for a hemostatic clip that can be used to efficiently ligate a severed vessel. The invention provides a hemostatic clip for closing a perforation in the wall of a vessel. The clip has a unitary clip body that defines an annular strip formed in



a saddle shape to adapt to the walls of the vessel. In a further aspect, the invention provides a hemostatic clip for ligating a severed vessel which has a unitary clip body that defines side by side and opposed pad members. An arcuate link member joins between and interconnects the pad members to clamp the lumen of a severed vessel closed. In a still further aspect, hemostatic clips are disclosed that can be applied by endoscopic methods through surgical access ports that dictate that the clip applicator approach the vessel parallel rather than normal to the longitudinal access of the vessel.

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SURGICAL VESSEL CLIPS AND METHODS FOR CLOSING VESSELS

Background of the Invention

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In the course of performing surgical procedures, the wall of a vessel is sometimes perforated and hemorrhaging occurs. To stop the hemorrhaging, the perforation in the wall of the vessel must be closed. In repairing the perforation, it is preferred that the vessel not be ligated, but rather that the perforation be closed while allowing fluid to flow unimpeded through the vessel. Conventional approaches to repair a perforation include suturing the tear. Suturing involves the surgical stitching of the perforation with a material such as silk, wire, or catgut. While this procedure is effective in closing the perforation, suturing has disadvantages. The suturing of vessel walls is tedious and time consuming, and it requires dexterity, which increases as the vessel to be sutured becomes smaller. Further, suturing requires that the area around the vessel to be sutured be exposed in order to provide access for the surgeon to stitch the vessel. As a result, the procedure is relatively complicated and has a significant threat of infection.

Another technique for temporarily controlling a perforation in the wall of a vessel is the use of clamps for pinching the walls of the vessel to close the perforation, and to stop the hemorrhaging. One such clamp is the so called "bull dog" clamp, which is a plastic clamp that the surgeon applies manually. This clamp has the disadvantages that flow in the vessel is restricted due to the pinching action, and the clamp must be applied manually without the benefit of an applier instrument. Again the area around the vessel must be exposed to provide adequate room for the surgeon to operate. Further, this clamp is intended only for temporary control of the perforation, and must at a later time be removed from the vessel in favor of a more permanent solution.

A generally U or V shaped clip with elongated arms is another known surgical clip for controlling a perforation in the wall of a vessel. These clips were designed, however, for the purpose of ligating a vessel, and are only used for controlling a perforation because no more suitable clip exists. The clips are usually constructed of metal and have the advantage that they can be applied with an endoscopic applicator, avoiding the requirement that the area around the vessel be exposed. However, these U or V shaped conventional clips have straight legs which, when compressed about the perforation to arrest the hemorrhaging, block a portion of the flow through the vessel. Examples of such clips include the surgical hemostatic clips of Gravener, U.S. Patent No. 5,501, 693; and of Phillips et al., US. Patent No. 5,509,920.

While U or V shaped surgical clips can be used to repair a perforation in the wall of a vessel, they are also used to ligate a severed vessel. In the former application, the objective is to repair the perforation in the vessel while continuing to provide

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unrestricted flow. In the latter, the objective is to completely close the severed vessel. and to stop the flow. These known clips are used generally as a precursor to surgically removing an organ. The vessel is initially clipped in two locations and then divided transversely between the two clips. One end of this vessel is connected to the organ or structure being removed and the other end remains in the body. Clips are applied to compressively cut off the flow through the open lumen, and to seal the vessel. Clips similar to those described in Gravener, supra, are used for this purpose. Ideally, these clips are applied so that their crimped length spans the lumen of the vessel (i.e. the applying instrument's shaft runs perpendicular to the vessel). However, in some endoscopic procedures, specifically a thoracic lung lobe resection, surgical access ports dictate the approach of the shaft of the clip applier instruments to the target vessel. Often, the vessels to be controlled are not oriented in a manner that allows the shaft of the applying instrument to be oriented perpendicular to the vessel. In fact, when performing this thoracic procedure through specific access ports, the vessels extend largely parallel to the axis of the shaft of the applying instrument. In such cases, a clip that traverses the lumen, while the shaft of the applying instrument is positioned substantially parallel to the vessel is desirable. Further, in an endoscopic situation involving a hemorrhage, it is important to control the hemorrhage quickly and precisely, without being limited by approach angles.

The disadvantages of the U or V shaped clip become apparent when applying clips to a vessel from certain orientations.

In light of the above, it is advantageous to provide surgical clips that are applied by endoscopic procedures through surgical access ports that limit the approach angles of the applying instrument. It is desirable that such a clip promotes the closure of a perforation in the wall of a vessel while at the same time introducing only a small reduction in the cross-sectional area of the vessel. Further, a surgical clip that can be applied perpendicular to the break in a severed vessel, when the applying instrument approaches the vessel "end on" or coaxially, is desirable. A surgical clip that eliminates or substantially reduces gaps in the closure of the vessel is also acknowledged to be beneficial and an advance in the art.

Objects of the Invention

It is thus an object of the invention to provide hemostatic clips that obviate disadvantages of the prior art.

It is a further object of the invention to provide a hemostatic clip that can be applied to close a perforation in the wall of a vessel.

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It is yet a further object of the invention to provide a hemostatic clip that can be applied to close a perforation in the wall of a vessel while introducing only a small reduction in the cross-sectional area of the vessel.

It is another object of the invention to provide a hemostatic clip that can be applied endoscopically through a surgical access port dictating a parallel approach rather than a perpendicular approach to the longitudinal axis of the vessel.

It is a further object of the invention to provide a hemostatic clip that can be applied to ligate a severed vessel.

It is a further object of the invention to provide a hemostatic clip that can be applied generally perpendicular to close a perforation that exists on the surface of a vessel.

It is yet a further object of the invention to provide a hemostatic clip that can be applied to ligate a severed vessel with reduced likelihood of gaps in the closure of the vessel.

It is another object of the invention to provide a hemostatic clip that can be advantageously applied to control an inadvertent tear or other breach or perforation in a vessel.

Other general and more specific objects of the invention will in part be obvious and will in part appear from the drawings and description which follow.

Summary of the Invention

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This invention addresses the need for hemostatic clips that are used advantageously when control of a vessel has not been obtained or when a vessel is lacerated or divided inadvertently. These clips urge closure of a perforation in the wall of a vessel, and reduce the necessity for suturing the vessel. In addition, the invention addresses the need for a hemostatic clip that can be used to ligate a severed vessel efficiently.

In one aspect, the invention provides a hemostatic clip for closing a perforation in the wall of a vessel. The clip has a unitary clip body that defines an annular strip formed in a saddle shape to adapt to the walls of the vessel. The clip includes a pair of opposed elongated strips which are formed in an arcuate shape. The elongated strips connect to arches, and together they define a closed-loop ring.

In another embodiment, the invention provides a hemostatic clip for closing a perforation in the wall of a vessel. The hemostatic clip has a unitary clip body with two opposed elongated strips which form an arcuate shape, and has a connecting arch that connects one end of one elongated strip to the opposed end of the other elongated strip.

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Both of the above clips advantageously engage side walls of a vessel by crimping the clip at the arch sections. Consequently, the clip applies pressure to the walls of the vessel to urge the perforation to close.

In a further aspect, the invention provides a hemostatic clip, for ligating a severed vessel, which has a unitary clip body that defines side by side and opposed pad members. An arcuate link member joins between and interconnects the pad members to clamp the lumen of a severed vessel closed.

In a still further aspect, the invention provides hemostatic clips that can be applied by endoscopic methods through surgical access ports that dictate that the clip applicator approach the vessel parallel rather than normal to the longitudinal access of the vessel.

Brief Description of the Drawings

The foregoing and other objects, features and advantages of the invention will be apparent from the following description and from the accompanying drawings, in which like reference characters refer to the same parts throughout the different views. The drawings illustrate principles of the invention and, although not to scale, show relative dimensions.

- FIG. 1 is a perspective view of a hemostatic clip in accordance with the present invention.
 - FIG. 1A is a perspective view of an alternate embodiment of a hemostatic clip in accordance with the present invention
 - FIG. 2 is a frontal view of the arcuate strips of the hemostatic clip of FIG. 1 and FIG. 1A.
- FIG. 3 is another perspective view of the hemostatic clip of FIG 1 showing a section line 4-4.
 - FIG. 4 is a sectional view of a hemostatic clip along section line 4-4.
 - FIG. 5 shows a vessel with a perforation and the application of the hemostatic clip of FIG. 1 for closing the perforation.
 - FIG. 6 is a perspective view of another embodiment of a hemostatic clip in accordance with the invention.
 - FIG. 7 shows a vessel with a perforation and the application of the hemostatic clip of FIG. 6 for closing the perforation.
 - FIG. 7A shows a vessel with a perforation and the application of two hemostatic clips as shown in FIG. 6 for closing the perforation.
 - FIG. 8 is another embodiment of a hemostatic clip in accordance with the present invention.

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FIG. 9 shows a vessel that is completely severed and the use of the clip of FIG. 8 for closing the severed vessel.

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FIG. 9A shows a vessel that is completely severed, and the application of hemostatic clips of FIG. 8 to ligate the vessel.

Description of Illustrated Embodiments

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The surgical clips of the invention are applied to vessels preferably through endoscopic procedures by an appropriate clip applicator to arrest the flow of fluid through either a perforation in the walls of the vessel or a severed vessel. Examples of vessels to which the teachings of this disclosure are particularly applicable are the blood vessels and the airways of a medical patient.

FIG. 1 shows a perspective view of a hemostatic clip 10 for closing a perforation in the wall of a vessel. The hemostatic clip 10 has a unitary clip body, constructed preferably from titanium. However, other materials such as stainless steel, tantalum, bioabsorbable polymers, and non-bioabsorbable polymers may be used. The hemostatic clip 10 includes a pair of arcuate strips 12 and 14 which are coupled together by a pair of arches 16 and 18 into a closed-loop ring In the embodiment shown in FIG. 1, arches 16 and 18 each have two legs forming generally a V shape. Arch 16 has legs 22 and 24. Similarly, arch 18 has legs 26 and 28. Leg 22 of arch 16 joins arcuate strip 12, forming an obtuse angle relative to leg 22. Leg 26 of arch 18 also joins arcuate strip 12, forming an obtuse angle relative to leg 26. Likewise, legs 24 and 28 join arcuate strip 14 to form an obtuse angle at the juncture. One of ordinary skill in the art will recognize that the angle between the arcuate strip and the leg depends in part on the diameter of the particular vessel. Semicircular strip 12 includes a vessel-contacting surface 32 for gripping one side of a perforation in the wall of a vessel. Likewise, arcuate strip 14 includes a vessel-contacting surface 34 for gripping the opposite side of the perforation in the wall of a vessel. The illustrated vessel-contacting surfaces 32 and 34 are recessed with grooves for efficient gripping of the clip to the wall of the vessel.

FIG. 1A shows an alternate embodiment of a hemostatic clip 15 in accordance with the invention. In this embodiment, hemostatic clip 15 is configured similar to hemostatic clip 10, and has a pair of arcuate strips 12' and 14' that are connected by arches 16' and 18'. The vessel-contacting surfaces 32' and 34' of the hemostatic clip 15 are different from the vessel-contacting surfaces 32 and 34 of hemostatic clip 10. Each vessel-contacting surface 32' and 34' has a smooth outer face 36' and an inner face consisting of sharps or teeth 38' that purchase into the wall of the vessel to promote a secure grip. Any trauma resulting from the purchase of teeth 38' into the vessel is sealed

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off by the smooth outer face 36' of the vessel-contacting surfaces, and does not spread throughout the wall of the vessel.

FIG. 2 shows a front view of arcuate strip 12. A frontal view of arcuate strip 14 has the identical geometry. FIG. 3 shows another perspective view of hemostatic clip 10, with a section line 4-4 that bisects arcuate strip 12 or 14. FIG. 4 is a sectional view of hemostatic clip 10 taken from the perspective of section line 4-4.

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The application of hemostatic clip 10 or 15 to close a perforation in the wall of a vessel is now described with reference to hemostatic clip 10. One of ordinary skill in the art will recognize that the application of hemostatic clip 15 is similar. FIG. 5 shows a vessel 30 with a perforation 32 in the wall of the vessel. Hemostatic clip 10 is applied preferably using an endoscopic clip applier. As hemostatic clip 10 is applied to the vessel 30, arcuate strip 12 grips the wall of the vessel above the perforation 32 and arcuate strip 14 grips the wall of the vessel below the perforation 32. Arches 16 and 18 of hemostatic clip 10 are crimped to bring the arcuate strips 12 and 14 into compressive engagement with the vessel, e.g. to pinch it, and thereby to adapt the clip to the wall of the vessel and to close perforation 32 as the surfaces of the wall above and below the perforation join. Grooves 32 and 34 on the underface of arcuate strips 14 and 12 grip the wall of the vessel to close the perforation and to attach the clip to the vessel.

The structure of the clip 10, including the configuration and the one or more materials of the portions that form the strips 12 and 14 and that form the arches 16 and 18, maintain the strips 12 and 14 compressively engaged with a vessel according to the extent of the crimping of the arches 16 and 18.

The hemostatic clip 10 and the hemostatic clip 15 allow closure of small and irregular perforations, lacerations or a rent that may occur in the wall of a thin walled vessel. These rents can occur on a tangential curve surface and cannot be controlled by straight clips.

If a tangential perforation or rent occurs in a large thin walled vessel, clamps are applied initially to stop the hemorrhage and to allow visualization of the rent or laceration. One or more hemostatic clips 10 are applied to enclose the laceration or rent and bring the walls of the vessel together in that one area, preserving flow in the main lumen beneath it. Once the rent has been occluded and controlled by one or more hemostatic clips 10, the clamps that are used to restrain blood flow can be removed.

FIG. 6, shows another hemostatic clip 60 in accordance with the present invention and which closes a perforation in the wall of a vessel. The hemostatic clip 60 has a unitary clip body, typically constructed preferably from titanium. However, other materials such as stainless steel, tantalum, bioabsorbable polymers, and non-bioabsorbable polymers may also be used. The hemostatic clip 60 includes a pair of

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opposed, curved arms 62 and 64 for gripping the wall of a vessel. The curvatures of arms 62 and 64 may be adapted for the size of the vessel to which it is applied. Arms 62 and 64 couple to a connecting arch 65. FIG. 6 shows that the connecting arch 65 includes an elongated strip with legs 66 and 67 that form a V shape. One of ordinary skill in the art will recognize that the connecting arch 65 may take alternative shapes and still successfully attain objects of the invention. Each illustrated arm 62 and 64 includes a vessel-contact face 68 and 69, respectively, for gripping the wall of a vessel.

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The application of the hemostatic clip 60 is now described with reference to FIG. 7, which shows a vessel 70 having a perforation 72 in the wall of the vessel. The hemostatic clip 60 is applied, preferably using an endoscopic clip applier. As the hemostatic clip 60 is applied to the vessel 70, the curved arm 62 of the clip grips the wall of the vessel above the perforation 72 and the curved arm 64 grips the wall of the vessel below the perforation 72. The hemostatic clip 60 is then crimped at the arch 65 to adapt the clip to the wall of the vessel and to close the perforation 72 as the clip applies pressure to join the surfaces of the wall on either side of the perforation. Grooved surfaces 68 and 69 on the underface of the curved arms 62 and 64 facilitate the gripping of the wall of the vessel to close the perforation and to secure the clip to the vessel.

The clip 60 of the invention is well suited and adapted for application in this manner with the applier instrument oriented transverse to the longitudinal axis A (FIGURE 7A) of the vessel being repaired. That is, the axis of the instrument approach to the vessel, and typically the shaft of the instrument, is aligned along an axis B transverse to the vessel axis A.

The hemostatic clip 60 can control a perforation, rent, laceration or other defect in a thin wall vessel. Clamps typically are used initially to control the bleeding, and allow the defect to be seen after the blood is suctioned. The application of the hemostatic clip 60 compresses the walls of the vessel at the site and separates the rent from the main channel. FIG. 7A shows two hemostatic clips applied to a vessel from opposing sides to separate a rent from the main channel of the vessel, thereby preserving the central flow.

FIG 8 shows a perspective view of a hemostatic clip 80 for closing a completely severed vessel according to another embodiment of the invention. The hemostatic clip 80 has a unitary clip body, constructed preferably from titanium. However, other materials such as stainless steel, tantalum, bioabsorbable polymers, and non-bioabsorbable polymers may also be used. The hemostatic clip 80 includes a pair of side by side and opposed pads 81 and 82 for gripping a severed vessel and at the same time for stopping the flow of fluid through the vessel. The pads 81 and 82 extend together through an arcuate structure. The illustrated arcuate structure has a pair of stems 83 and

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84 which connect to respective pads 81 and 82. The stems 83 and 84 further couple to an arch structure 86. In one embodiment of the invention, the arch structure 86 forms a V shape. However, one of ordinary skill in the art will recognize that the arch structure 86 may take alternative shapes and yet still attain objects of the invention within the scope of the invention. In another embodiment of the invention, the pad 81 and the stem 83 form a T shape. Likewise, the pad 82 and the stem 84 form a T shape. In another embodiment, the pad and stem pairs form an L shape. The pads 82 and 81 face opposite to each other. Each pad 81 and 82 includes an opposed face 87 and 88 to contact the wall of the vessel.

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The application of the hemostatic clip 80 is now described with reference to FIG. 9, which shows a severed vessel 90 that is to be ligated to stop a hemorrhage. The hemostatic clip 80 is applied using preferably an endoscopic clip applier in an "end on" approach to the vessel 90. With this direction of approach, the axis of the applier instrument, and hence typically the shaft of the instrument, is substantially parallel to the longitudinal axis C of the vessel, as shown. The opposing pad members 81 and 82 are applied perpendicular to the flow of fluid within the vessel and grip the wall of the vessel above and below the cut. The clip applier crimps the arch structure 86, deforming the clip and bringing the opposed pad members 81 and 82 closer together and to grasp between them portions of a vessel wall. This adapts the clip to the wall of the vessel and closes the lumen of the vessel, since the opposed pad members pressure the surfaces of the wall above and below the cut to join together. The grooved surfaces 87 and 88 on the opposed faces of the pads 81 and 82 grip the wall of the vessel to close the lumen of the vessel and to fixedly attach the clip to the vessel. In further embodiment of the invention, the stems 83 and 84 have varying lengths, so that when the hemostatic clip 80 is positioned alongside a similar clip having shorter stems 83 and 84, the pads 81 and 82 of the longer clip extend beyond those of the shorter clip. By employing the shorter clips and the longer clips in an alternating fashion, an overlapping line of ligation is created to achieve better hemostasis. FIG. 9A shows multiple hemostatic clips 80 that are positioned in a staggered arrangement to efficiently close off the vessel and to eliminate gaps in the closure, in a manner that diminishes leakage from the vessel.

It is thus seen that the invention efficiently attains the objects set forth above, among those made apparent from the preceding description. Since certain changes may be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings be interpreted as illustrative and not in a limiting sense.

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It is also to be understood that the following claims are to cover all generic and specific features of the invention described herein, and all statements of the scope of the invention which, as a matter of language, might be said to fall therebetween.

Having described the invention, what is claimed as new and desired to be secured by Letters Patent is:

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We claim:

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1. A hemostatic clip for closing a perforation in the wall of a vessel said clip comprising,

5 a unitary clip body defining first and second opposed elongated strip 10

portions, each of said first and second elongated strip portions having an arcuate shape, and a first connecting arch portion for connecting a first end of said first elongated strip portion to said opposed end of the second elongated strip portion and a second connecting arch portion for connecting a second end of said first elongated strip portion to the said opposed end of said second elongated strip portion.

- 2. The hemostatic clip of claim 1 wherein each of said first and second arch portions has a V - shaped form for adapting the clip to the wall of the vessel.
- 3. The hemostatic clip of claim 1 wherein the clip body is of a material selected from the group consisting of stainless steel, tantalum, titanium, bioabsorbable polymers and nonbioabsorbable polymers.
- 20 The hemostatic clip of claim 1 wherein each of said first and second elongated strip 4. portions has opposed side walls defining opposing boundaries and an elongated vessel-contacting surface thereon.
- 5. The hemostatic clip of claim 4 wherein each of said first and second elongated 25 vessel-contacting surfaces includes grooves for gripping the wall of the vessel.
 - 6. The hemostatic clip of claim 4 wherein each of said first and second elongated vessel-contacting surfaces includes an outer smooth face adjacent to an inner face consisting of teeth for gripping the vessel.
 - 7. A hemostatic clip for ligating a severed vessel, said clip comprising, a unitary clip body having side by side and opposed pad members and an arcuate link member joined between and interconnecting said pad members.
 - The hemostatic clip of claim 7 wherein said arcuate link member includes 8. opposing stems connected by an arch portion.

- 9. The hemostatic clip of claim 7 wherein each of said pads is substantially coextending.
- 5 10. The hemostatic clip of claim 7 wherein each of said pads has opposed faces with opposing boundaries and a vessel-contacting surface thereon for cooperatively gripping the wall of the vessel.
- 11. The hemostatic clip of claim 7 wherein the clip is of a material selected from the group consisting of stainless steel, tantalum, titanium, bioabsorbable polymers and nonbioabsorbable polymers.
 - 12. The hemostatic clip of claim 7 wherein the arch member is a V shape.
- 15 13. The hemostatic clip of claim 9 wherein said pad member and said stem are a T shape.
 - 14. The hemostatic clip of claim 11 wherein each of said vessel-contacting surfaces includes complementary grooves for gripping the wall of the vessel.
 - 15. A hemostatic clip for closing a perforation in the wall of a vessel, said clip comprising,

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a unitary clip body having a first and a second opposed elongated strip portions, each of said first and second elongated strip portions having a substantially curved shape, said clip body including a connecting arch portion for connecting one end of the said first elongated strip portion to the said opposed end of the second elongated strip portion.

- 16. The hemostatic clip of claim 15 wherein said connecting arch portion has a V shape for adapting the clip to fit the wall of the vessel.
 - 17. The hemostatic clip of claim 15 wherein the clip is of a material selected from the group consisting of stainless steel, tantalum, titanium, bioabsorbable polymers and nonbioabsorbable polymers.

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- 18. The hemostatic clip of claim 15 wherein each of said first and second elongated strip portions has opposed side walls defining opposing boundaries and an elongated vessel-contacting surface thereon.
- The hemostatic clip of claim 18 wherein the each of said first and second elongated vessel-contacting surfaces includes grooves for gripping the walls of the vessel.
 - 20. A hemostatic clip for closing a perforation in the wall of a vessel, said clip comprising,

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a unitary clip body defining an annular strip formed in a saddle shape to adapt to the walls of said vessel.

- 21. The hemostatic clip of claim 20 wherein said annular strip includes a vessel-contacting face.
- 22. The hemostatic clip of claim 20 wherein said clip is of a material selected from the group consisting of stainless steel, tantalum, titanium, bioabsorbable polymers and nonbioabsorbable polymers.
- 20 23. The hemostatic clip of claim 21 wherein said vessel-contacting face includes grooves for gripping said vessel wall.
 - 24. A method for ligating a severed vessel having a lumen for containing a flow of fluid therethrough, the method comprising the steps of,

providing a hemostatic clip, having opposed co-extending pads which are normal to an arch portion, and

positioning said hemostatic clip such that said co-extending pads are positioned perpendicular to said flow, to encompass said lumen, and

crimping said arch of said hemostatic clip to compressively engage said pads about said lumen to close said severed vessel.

35 25. The method for ligating a severed vessel as recited in claim 24 including the further steps of,

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providing a plurality of hemostatic clips, having opposed co-extending pads which are normal to an arch portion, and

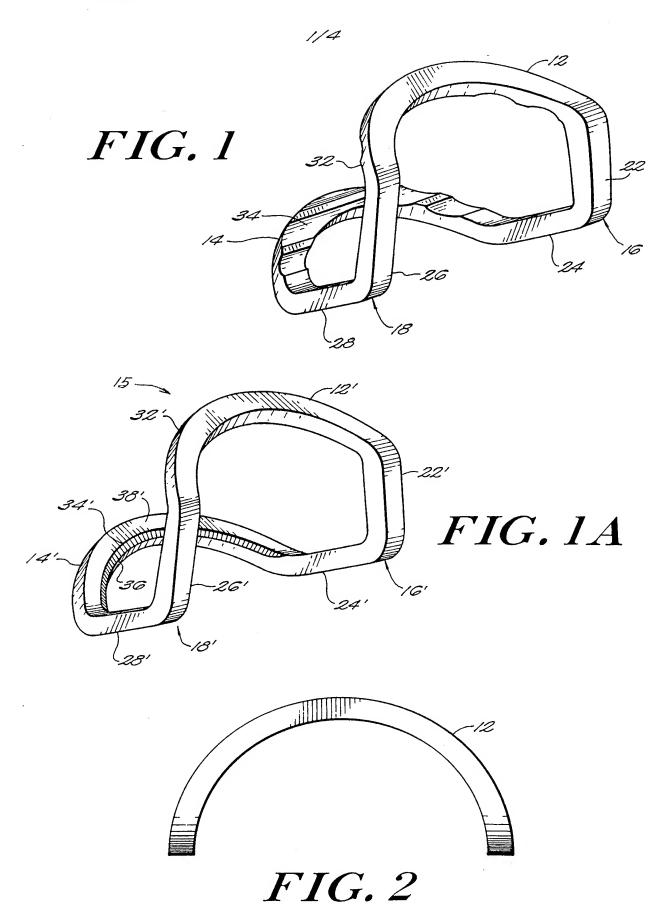
positioning said like hemostatic clips in a staggered arrangement to encompass said lumen

26. The method of closing a perforation in the wall of a vessel comprising the steps of, positioning a hemostatic clip having an arch portion connected to first and second curved extending arms, opposed to each other, such that the first extending arm is positioned above the perforation and the second extending arm is positioned below the said perforation, and

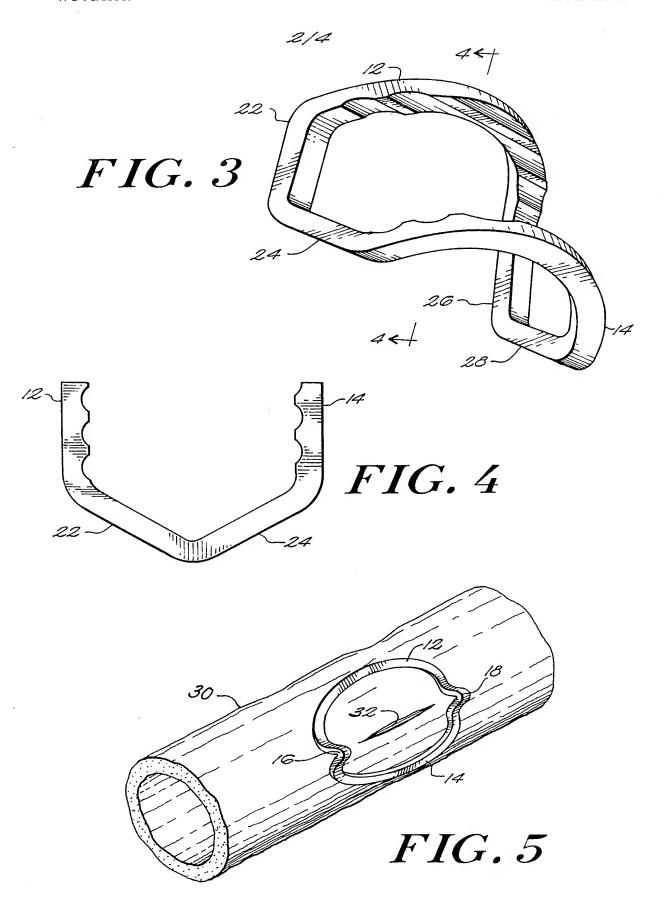
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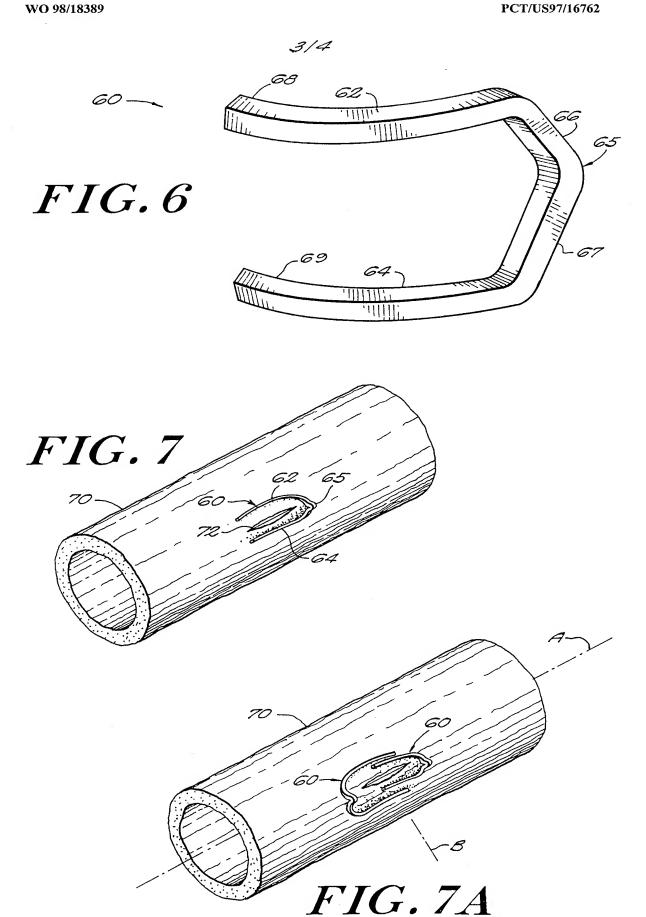
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- crimping said arch of the hemostatic clip to urge said perforation to close.
- The method of claim 26 further comprising the steps of, positioning a second hemostatic clip opposed to said first hemostatic clip, said second hemostatic clip having an arch portion connected to first and second curved extending arms opposed to each other such that the first extending arm is positioned above the perforation and the second extending arm is positioned below the said perforation, and
 - crimping said arch of said second hemostatic clip to urge said perforation to close.
- 25 28. The method of claim 26 wherein said first and second extending arms are curved to adapt to the wall of said vessel.



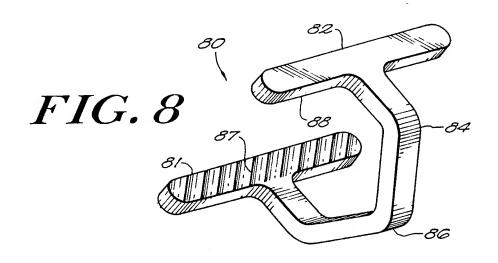
SUBSTITUTE SHEET (RULE 26)

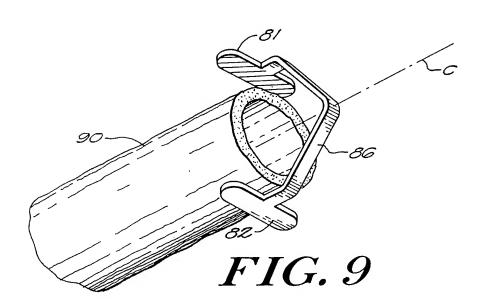




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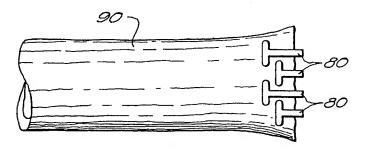


FIG. 9A

SUBSTITUTE SHEET (RULE 26)

International Application No PCT/US 97/16762

A. CLA			SUBJECT	MATTER
IPC	6 <i>F</i>	\61B1	7/122	

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) $IPC \ 6 \ A61B$

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Х	US 3 856 016 A (DAVIS) 24 December 1974	1-6, 20-23
	see figure 2	
X	US 3 856 018 A (PERISSE) 24 December 1974 see figures 13,19	1,20
X A	EP 0 399 741 A (ETHICON) 28 November 1990 see abstract; figure 1C	15-19 6,23
Α	US 5 026 379 A (YOON) 25 June 1991	1,5,6, 20,23
	see column 8, line 52 - line 55; figure 20A	20,20
Α	GB 2 150 440 A (KIRSCH) 3 July 1985 see abstract; figure 3	1,15,20

X Further documents are listed in the continuation of box C.	Patent family members are listed in annex.
 Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed 	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family
Date of the actual completion of the international search	Date of mailing of the international search report
5 December 1997	2 0. 03. 98
Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	BARTON, S

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		PC1/03 97/10/02	
	tion) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	
X	US 3 209 754 A (BROWN) 5 October 1965 see figures 1-3	15	
A	US 4 917 677 A (MCCARTHY) 17 April 1990		
Ρ,Χ	US 5 609 599 A (LEVIN) 11 March 1997 see figure 1	1,20	
P,X	US 5 667 518 A (PANNEL) 16 September 1997 see figures 6-9	15	
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International application No.

PCT/US 97/16762

Box I	Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This Inte	rnational Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X	Claims Nos.: 24-28 because they relate to subject matter not required to be searched by this Authority, namely: PCT_RULE_39.1 (IV)
2.	Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.	Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box II	Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)
This Inte	ernational Searching Authority found multiple inventions in this international application, as follows:
1. 2.	CLAIMS: 1-6, 15-23 CLAIMS: 7-14
1.	As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.	As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3	As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid; specifically claims Nos.:
4. X	No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-6, 15-23
Remarl	The additional search fees were accompanied by the applicant's protest. No protest accompanied the payment of additional search fees.

Information on patent family members

Interna...onal Application No
PCT/US 97/16762

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 3856016 A	24-12-74	US 3954108 A	04-05-76
US 3856018 A	24-12-74	NONE	
EP 399741 A	28-11-90	US 4976722 A AU 633096 B AU 5579890 A CA 2017273 A DE 69022115 D DE 69022115 T ES 2078307 T GR 1000780 B IE 68849 B JP 3049744 A PT 94113 B	11-12-90 21-01-93 22-11-90 22-11-90 12-10-95 22-02-96 16-12-95 30-12-92 24-07-96 04-03-91 28-05-97
US 5026379 A	25-06-91	US 5334209 A US 5665100 A US 5217473 A US 5217030 A US 5226908 A	02-08-94 09-09-97 08-06-93 08-06-93 13-07-93
GB 2150440 A	03-07-85	US 4586503 A CA 1251113 A DE 3443367 A FR 2557448 A SE 454321 B SE 8406053 A US 4929240 A US 4733664 A	06-05-86 14-03-89 13-06-85 05-07-85 25-04-88 02-06-85 29-05-90 29-03-88
US 3209754 A	05-10-65	NONE	
US 4917677 A	17-04-90	NONE	
US 5609599 A	11-03-97	NONE	
US 5667518 A	16-09-97	NONE	